IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MICHELLE BARNES,	§	
Plaintiff,	§	**CIVIL ACTION NO. _____**
	§	**JURY TRIAL DEMANDED**
V.	§	
	§	
TEVA WOMEN'S HEALTH, INC.,	§	
TEVA BRANDED PHARMACEUTICALS R&D	§	
INC., TEVA PHARMACEUTICALS USA, INC.	§	
AND TEVA PHARMACEUTICAL INDUSTRIES,	§	
LTD.	§	
Defendants.	§	
	§	

PLAINTIFF'S ORIGINAL COMPLAINT

TO THE HONORABLE UNITED STATES DISTRICT COURT:

COMES NOW, **MICHELLE BARNES** ("Plaintiff"), complaining of **TEVA WOMEN'S HEALTH, INC.** ("Teva Women's"), **TEVA BRANDED PHARMACEUTICALS R&D, INC.** ("Teva R&D"), **TEVA PHARMACEUTICALS USA, INC.** ("Teva USA"), **and TEVA PHARMACEUTICAL INDUSTRIES, LTD.** ("Teva") and for causes of action would respectfully show unto this Honorable Court as follows:

I.
INTRODUCTION

1. Plaintiff files this Complaint against the Defendants for personal injury suffered as a result of a defective Paragard Intrauterine Device which is researched, manufactured, merchandised, advertised, promoted, labeled, analyzed, tested, distributed packaged, marked, and sold by Defendants, as more fully detailed herein below.

2. The Paragard IUD device that was inserted into Plaintiff was defective and/or unreasonably dangerous because it was not reasonably safe for its intended use, as it subjected Plaintiff to risks which exceeded its benefits, it was defective in design and formulation thereby making it more dangerous than other forms of birth control, and more dangerous than an ordinary consumer would expect. Its risks exceeded those associated with the medical reasons for which it was prescribed, and because the Paragard IUD was otherwise defective and unreasonably dangerous as set forth herein.

II.
PARTIES

3. Plaintiff is and was at all times relevant hereto an individual residing in the United States and a resident of the State of Texas. Plaintiff suffered injuries that required multiple surgeries as a result of using Defendants' Paragard IUD. She may be reached through her attorney of record, Marcus L. Stevenson, The Stevenson Law Firm, PC, 6302 W. Broadway St., Suite 120, Pearland, TX 77581.

4. Defendant, Teva Women's Health, Inc., is a Delaware Corporation whose principal office is located at 41 Moores Rd., Frazer, PA 19355. Its registered agent is Corporate Creations Network, Inc. 3411 Silverside Road, Tatnall Building, #104, Wilmington, DE 19810.

5. Defendant, Teva Branded Pharmaceuticals Products R&D, Inc., is a Delaware Corporation whose principal office is located at 41 Moores Rd., Frazer, PA 19355. Its registered agent is Corporate Creations Network, Inc. 3411 Silverside Road, Tatnall Building, #104, Wilmington, DE 19810.

6. Defendant, Teva Pharmaceuticals USA, Inc., is a Delaware Corporation whose principal office is located at 1090 Horsham Road, North Wales, Pennsylvania. Its registered agent

is Corporate Creations Network, Inc. 3411 Silverside Road, Tatnall Building, #104, Wilmington, DE 19810.

7. Defendant, Teva Pharmaceuticals Industries, Ltd., is an Israeli company headquartered in Petah Tikva, Israel. Teva is a global pharmaceutical corporation and the largest generic drug manufacturer in the world. Teva conducts business all over the world, including in the U.S. Teva is responsible for the management of defendants Teva Pharmaceutical USA, Inc. and Teva Women's Health, Inc. Its principal office is located at 425 W. Privet Rd., Horsham, Pennsylvania 19044. Pursuant to the Hague Convention on Service Abroad, Teva may be served with service of process at its corporate headquarters located at 5 Basel St., P.O. Box 3190, Petach Tikva 4951033, Israel.

III.
JURISDICTION AND VENUE

8. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332 because complete diversity exist between Plaintiff, who is a citizen of the State of Texas, which is different from the states where the Defendants are incorporated and have their principal place of business, and the amount in controversy for the Plaintiff exceeds $15,000 exclusive of interest and costs.

9. Venue is proper in this district under 28 U.S.C. § 1391(b) because the acts, events, or omissions giving rise to this claim occurred in Harris County, Texas, which falls within the United States District Court for the Southern District of Texas, Houston Division.

IV.
FACTUAL BACKGROUND

10. At all relevant times Defendants through their agents, servants, and employees, designed researched, manufactured, labeled, packaged, promoted, marketed and/or sold Paragard IUD.

11. At all times relevant, Defendants engaged in extensive mass media direct-to-consumer promotion, education and advertising of Paragard Intrauterine Devices (IUD) for the purpose of increasing sales and stimulating consumer requests for Paragard Intrauterine Devices independent of the advice of medical professionals.

12. At all times relevant, Defendant and their aggregates, associates, and partners, and each of them, were the agent, servant, employee, assignee, permissive user, successor in interest or joint venture of the other, and were acting within the time, purpose or scope of such, or employment or permission; and all acts or omissions alleged herein of each such defendant were authorized, adopted, approved or ratified by each of the Defendants.

13. In January 2007, Plaintiff underwent a procedure to have a Paragard IUD inserted as her form of birth control which stayed in place for approximately nine years. According to the Paragard website, this device has a lifespan of ten (10) years.

14. In December 2015, Plaintiff began to experience symptoms of urinary tract infections and symptoms of burning pain and pelvic pain. She went to the ER for this pain. Upon examination, it was determined that Plaintiff's IUD had migrated into her lower uterine segment.

15. On January 18, 2016, Plaintiff underwent removal of the IUD by her gynecologist at the time, the IUD "disintegrated" and Plaintiff needed emergency surgery as she was hemorrhaging. IUD fragments embedded into Plaintiff's uterus and other areas.

16. Plaintiff needed several surgical procedures to remove the IUD fragments. Following her initial surgery, Plaintiff underwent surgeries on or about January 25, 2016 (second surgery to remove additional fragments vaginally), on or about September 29, 2016 (third surgery to remove the fragments vaginally), however, the doctor couldn't get to the fragments at this time, so she stated she'd have to perform surgery through the umbilical. On or about September 30, 2016, Plaintiff underwent a fourth surgery to remove remaining fragments. Again, the doctor was

unable to remove all fragments and told Plaintiff she had to have a hysterectomy. October 19, 2016, Plaintiff underwent a fifth surgery involving a total hysterectomy and bilateral salpingectomy.

17. The Paragard IUD was marketed by Defendants as safe and effective promising fewer side effect than other birth controls.

18. The marketing and promotion efforts of the Defendants, their advertisers, and sales force serve to overstate the benefits of Paragard IUD, and minimize and downplay the risks associated with the IUD. These promotional efforts were made while fraudulently withholding important safety information from the physicians and the public.

19. The product warnings for Paragard in in effect during the relevant time period were vague, incomplete or otherwise wholly inadequate, both substantially and graphically, to alert prescribing physicians as well as consumer patients of the actual risks of the device crumbling or disintegrating upon removal.

20. Based on these representations, upon which Plaintiff and her treating physicians relied, including the omission from the Paragard labeling of the danger of increased risk of adverse risks of serious injury to her uterus and other organs.

21. As a direct result of Plaintiff's use of Paragard IUD, Plaintiff developed serious health problems. In addition, the conduct of the Defendants has caused Plaintiff further damage, including but not limited to pain, suffering, mental anguish, loss of the enjoyment of life, medical expenses and other out-of-pocket losses.

V.
CAUSES OF ACTION

A. COUNT ONE – STRICT LIABILITY

22. Plaintiff hereby adopts, incorporates, restates and re-alleges paragraphs 1 through 21, inclusive, with regard to all causes of action.

23. Plaintiff alleges that Defendants are in the business of designing, testing, manufacturing, labeling, advertising, promoting, selling and distributing the Paragard IUD.

24. Defendants placed the Paragard IUD in the stream of commerce for use by the public, including Plaintiff.

25. Plaintiff used the Paragard IUD as a birth control method, and resulted in great pain and suffering, removal of her uterus, cervix and fallopian tubes, and now has the inability to conceive, as a result of the insertion, migration, embedment, disintegration and removal of Defendants defective device.

26. Prior to the insertion, migration and removal of the Paragard IUD, Plaintiff did not have any of the problems outlined in paragraph 25. Plaintiff chose the Paragard IUD as her birth control method after researching the product on their website and relying on communications therein from her physician. As a result of the Defendants' defective device, she suffered great bodily and psychological injury.

27. The injuries that Plaintiff complains of, are different from the ones that are listed on the warning label on the Paragard IUD. She has experienced depression, hair loss, extreme menopausal symptoms, bladder leaks, sleep difficulties, terror and severe anxiety, bowel issues, sexual dysfunction, back, neck and shoulder pain, exhaustion, and nausea.

28. The injuries that Plaintiff suffered as a result of using Defendant's defective device renders the product to be unreasonably dangerous. When the product is working properly the warning label states that it can stay in place for ten years to prevent pregnancy.

29. Plaintiff had the Paragard IUD installed for nine (9) years before having to have it surgically removed. Plaintiff is suffering bodily and psychological injury from the insertion, migration, disintegration, and removal of Defendant's defective device. The injuries were

catastrophic, current and continuing. Defendants' product is unreasonable dangerous when used for the purpose that it was intended for.

30. The defect in Defendants' Paragard IUD caused the injury. No privity between Plaintiff and Defendants, the defect had to have happened at the time of production and at the time it left the manufacturer.

B. COUNT TWO – FAILURE TO WARN

31. Plaintiff hereby adopts, incorporates, restates and re-alleges paragraphs 1 through 30, inclusive, with regard to all causes of action.

32. Defendants did not adequately warn of particular risks that was known or knowable, in light of the generally recognized and prevailing best scientific and medical knowledge, at the time of manufacture and distribution.

33. Defendants knew that their product was defective because they document a partial list of the risks on the warning label of the device. Defendants' warning label only lists about eight risks associated with their product, and they were by no means exhaustive.

34. Defendants' warning label and website warned of some risks associated with their product. Plaintiff contends that the warning was inadequate, unclear, and ambiguous. The warning on the label speaks of the following risks: Intrauterine pregnancy, Ectopic pregnancy, Pelvic infection, immunocompromise, Embedment, Perforation, Expulsion, and Wilson's disease.

35. After reading Defendants' warning label on the Paragard IUD, consumers, including Plaintiff, and/or attending physicians would have to pile inference upon inference to be able to conclude that by inserting their product, having it migrate, and then having it surgically removed, that Plaintiff would be in a constant state of pain and suffering, requiring multiple medications, and removal of her uterus, ovaries and fallopian tubes.

36. Defendants' warning label is misleading and inadequate in that it did not state that dangers of the device from embedding and perforation. Defendants' device problems could last for years, astronomical high medical expenses, for the removal of an embedded device and continued care could cost millions of dollars.

37. Plaintiff argues that Defendants' warning label that was furnished was not accurate, clear or unambiguous. The warnings did not adequately convey information regarding risks that Plaintiff suffered. The information in the brochure, and reflected in medical literature and on their website in fact tried to minimize or negate any warnings present.

38. Because of the inadequate warning to the prescribing physician and to the Plaintiff, Plaintiff was caused to sustain major bodily injury apart and beyond the warning label on pain, suffering, and medical expenses.

39. The warning label does not elaborate on the degree of injury or the risks that the Plaintiff has experienced, including but not limited to partial removal of organs, loss of livelihood, loss of consortium, loss of capacity for enjoyment of life, extensive medical care, depression, hair loss, extreme menopausal symptoms, bladder leaks, sleep difficulties, terror and severe anxiety, bowel issues, sexual dysfunction, back, neck and shoulder pain, fatigue, and nausea.

40. Failure of Defendants to warn Plaintiff was the proximate cause of the injury. If Plaintiff had been warned of the risks, Plaintiff would have chosen a safer birth control method and avoided all risks and injuries associated with the Paragard IUD.

41. But for the inadequate warning, Plaintiff would have never utilized the Paragard IUD if Plaintiff knew that it had so many other risks associated therewith. The warning label should at the very least add that the device should be monitored by a physician at regular intervals to minimize the severity and frequency of the risks located on the warning label, as well as other risks not listed thereon.

42. Defendants' warning for the Paragard IUD is incomplete at best, as the risks lead directly to other major problems which are not mentioned; and therefore, inadequate as a matter of law.

43. Plaintiff's injuries, wounds, and losses were, are, and will be, directly, and proximately caused by the Defendants' failure to adequately warn consumers including Plaintiff of the defective condition of their defective Paragard IUD, and the other health problems that it could lead to.

C. COUNT THREE – DESIGN DEFECT

44. Plaintiff hereby adopts, incorporates, restates and re-alleges paragraphs 1 through 43, inclusive, with regard to all causes of action.

45. Plaintiff alleges that Defendants are in the business of designing, testing, manufacturing, labeling, advertising, promoting, selling and distributing the Paragard IUD.

46. Knowing that Paragard IUD was defective, Defendants placed the device in the stream of commerce for use by the public, including Plaintiff. Defendants knew of the defects in the product because a partial list of the risks associated therewith is listed on the product's warning label.

47. Plaintiff chose to use Paragard IUD for her birth control method. This was the intended use of the product.

48. Knowing that Paragard IUD was defective and unreasonable dangerous, Defendants placed the product in the stream of commerce for use by the public, including Plaintiff. Defendants knew that the product was defective and created unreasonably dangerous condition, because they added a partial list of the risks associated therewith on the warning label.

49. Defendants' product was defective and created an unreasonable dangerous condition in that the Paragard IUD malfunctioned during the normal use and operation of the

product. The device was designed to stay in place for 10 years but only was able to stay in place for nine (9) years before it malfunctioned.

50. As a result of the Paragard IUD malfunctioning, Plaintiff suffered migration requiring partial removal thereof, the disintegration of the IUD, extended hospital stays and continuous medication monitoring for pain and suffering, loss of consortium, and reduction of quality of life.

51. The insertion, migration thereof the same, and removal of the Paragard IUD, was the proximate and actual cause of Plaintiff's injuries.

52. Defendants' Paragard IUD was unreasonably dangerous because of the medical conditions Plaintiff developed. This outcome was unreasonable because there were other, safer birth control methods available to the Plaintiff.

53. Plaintiff's injuries, wounds, and losses were, are, and will be, directly, and proximately caused as a result of the design defects of Defendants Paragard IUD.

D. COUNT FOUR – MANUFACTURER'S DEFECT

54. The allegations set forth in paragraphs 1 through 53 are herein incorporated by reference, the same as if fully set forth verbatim for any and all purposes of this complaint.

55. Plaintiff alleges that Defendants are in the business of designing, testing, manufacturing, labeling, advertising, promoting, selling and distributing the Paragard IUD.

56. Defendants have a duty to place goods into the stream of commerce that are safe to be used by the public including the Plaintiff.

57. The Paragard IUD was used as a birth control method and malfunction during the normal operation of the product.

58. The product was defective when it left the manufacturer. Plaintiff and manufacturer and/or Defendants did not have any privity of contract. Plaintiff was fitted with the device by her physician. The defect had to exist at the time the product left Defendants.

59. Plaintiff was injured, including but not limited to experienced great pain and suffering, resulting in removal of her uterus, cervix and fallopian tubes as a result of the insertion, migration, disintegration and removal of Defendant's defective Paragard IUD. Plaintiff continues to experience depression, hair loss, extreme menopausal symptoms, bladder leaks, sleep difficulties, terror and severe anxiety, bowel issues, sexual dysfunction, back, neck and shoulder pain, fatigue, and nausea.

60. Plaintiff's injuries, wounds, and losses were, are, and will be, directly, and proximately caused as a result of the manufacturer's defects of Defendants' Paragard IUD.

E. COUNT FIVE - NEGLIGENCE

61. The allegations set forth in paragraphs 1 through 60 are herein incorporated by reference, the same as if fully set forth verbatim for any and all purposes of this complaint.

62. Plaintiff alleges that Defendants are in the business of designing, testing, manufacturing, labeling, advertising, promoting, selling and distributing the Paragard IUD.

63. At all relevant times, Defendants, owed a duty to consumers including Plaintiff to design, manufacture, test, inspect, produce, sell, and distribute Paragard IUD s that were safe for use to consumers, including Plaintiff without an unreasonable risk of harm to others.

64. Defendants breached that duty by knowingly placing the unreasonably defective Paragard IUD into the stream of commerce for consumers, including Plaintiff, to choose as a birth control method, especially when there were other safer birth control methods available and on the market. Defendants failed to discharge these duties and Plaintiff was caused to sustain injury, pain, and suffering.

65. Defendants knew or should have known that by placing their defective, unreasonably dangerous product into the stream of commerce would cause consumers, including Plaintiff to become injured by their Paragard IUD. The product warning label includes that the device can cause peroration of the uterus, embedding into organs, and that it may need to be surgically removed. There is a whole host of other risks involved with the device that the manufacturer failed to list, showing further negligence.

66. Plaintiff used the Paragard IUD for the purpose that it was intended for which was for which was as a birth control method. The insertion, migration, disintegration, and surgical removal thereof the Defendants' Paragard IUD is the actual, legal and proximate cause of the Plaintiff's injuries.

67. Plaintiff was injured, including but not limited to experienced great pain and suffering, resulting in removal of her uterus, cervix and fallopian tubes as a result of the insertion, migration, disintegration and removal of Defendants' defective Paragard IUD. Plaintiff continues to experience depression, hair loss, extreme menopausal symptoms, bladder leaks, sleep difficulties, terror and severe anxiety, bowel issues, sexual dysfunction, back, neck and shoulder pain, exhaustion, and nausea.

68. Plaintiff's injuries, wounds, and losses were, are, and will be, directly, and proximately caused by the negligence of the Defendants without any negligence on the part of the Plaintiff.

69. As a direct and proximate result of the Paragard IUD unreasonably dangerous and defective condition, as well as the Defendants' other negligent acts or omissions, the Plaintiff has been, is now, and will in the future be compelled to present herself to various physicians for medical care and treatment and has, is, and will incur expenses for medical care and treatment in the future.

70. Plaintiff's injuries, wounds, and losses were, are, and will be, directly, and proximately cause are a result of the design defects of Defendants' Paragard IUD.

VI.
DAMAGES

71. Plaintiff hereby adopts, incorporates, restates and re-alleges paragraphs 1 through 70, inclusive, with regard to all causes of action.

72. As a proximate and/or producing result of Defendants' conduct, Plaintiff suffered, sustained and incurred, and in reasonable medical probability will continue to suffer, sustain and incur, the following injuries and damages, among others:

a. Physical pain sustained in the past and, in reasonable probability, that will be sustained in the future;
b. Mental anguish sustained in the past and, in reasonable probability, will be sustained in the future;
c. Physical pain and suffering sustained in the past and that, in reasonable probability, will be sustained in the future;
d. Disfigurement; and
e. Exemplary damages.

VII.
JURY DEMAND

73. Plaintiff respectfully demands trial by jury and has tendered the appropriate fee for the same.

VIII.
PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff respectfully requests Defendants to be cited to appear and answer herein, and that upon final trial hereof, the Court award the relief against Defendants, considering each count for pain and suffering, physical impairment, mental anguish, inconvenience, loss of capacity for enjoyment of life, compensatory, treble, punitive damages, together with interest, costs of suit, attorneys fees, and all such other relief as the court deems proper.

Respectfully submitted,

THE STEVENSON LAW FIRM, PC

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